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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,396	03/24/2004	Jeffrey B. Skiba	PT-2453-US-DIV	3326
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NORMAN F. HAINER, JR. SMITH & NEPHEW, INC. 150 MINUTEMAN ROAD ANDOVER, MA 01801			EXAMINER WOO, JULLAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 03/27/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,396

Applicant(s)

SKIBA ET AL.

Examiner

Julian W. Woo

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 6-36, 51, 52, 55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 11, 14, 15, 19, 20, 25, 26, 30, 32-36, 51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6, 7, 9, 12, 13, 16-18, 21-24, 27-29, 31, 55 and 57-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 8, 2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3, 6, 7, 9, 12, 13, 16-18, 21-24, 27-29, 31, 55, and 57-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to base claims 1 and 55, the specification does not describe a suturing device including, inter alia, a handle, a shaft, and a tip, where the tip is immovable relative to the handle and the shaft. With respect to base claim 22, the specification does not describe a suturing device, where the device does not allow for independent positioning of the needle when the needle is attached to the shaft. On the

contrary, in the specification, under "SUMMARY OF THE INVENTION," page 2 states that the "tip may be detached from the suturing device and replaced by another tip," and that the "position of each tip is adjustable relative to the shaft of the suturing." In other words, the specification describes a tip that is movable relative to the handle and the shaft and a device that allows for independent positioning of the needle when the needle is attached to the shaft.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21-24, 27-29, 31, and 58-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not certain how the tip is "selectively detachable from the shaft" when the tip is said to be "immovable relative to the handle and the shaft. Also, it is not certain how the device "does not allow for independent positioning of the needle when the needle is attached to the shaft" when the needle is said to be "detachable" from the shaft.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1, 3, 6, 7, 9, 12, 13, 16-18, 55, 57, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. (5,562,685) in view of Beyer et al. (4,563,961), and further in view of Zocher (3,469,548). Mollenauer et al. disclose the invention substantially as claimed. Mollenauer et al. disclose, at least in figures 1 and 12 and in col. 9, line 37 to col. 10, line 5; a suturing device including a handle (102 or 12) extending along axial direction, an elongated shaft (104) with a distal end and extending along an axial direction, a sharpened tip (106 or 104) attached to (i.e. joined to) a distal end of the elongated shaft, and a detachable suture (110) that is a length of material; where the sharpened tip (106) includes an elongated opening (108) configured to trap a suture at a selected point and including a curved portion and configured to permit suture to pass lengthwise through the opening, where the tip is immovable relative to the handle and the shaft, where the sharpened tip (104) has a hooked configuration or is angularly bent relative to the shaft in a selected direction, where the sharpened tip is curved at least partially about the distal end of the shaft (102) or extends at an angle and to one side of the distal end, where the sharpened tip (104) extends at least partially forward from the distal end with a concave configuration,

where the sharpened tip is angularly bent about a tip axis that is non-parallel with the axial direction (i.e., each coil portion of the needle, including the tip, is angled with respect to the axial direction) and is curved about the axial direction; and where the handle is located in-line with the shaft (i.e., the longitudinal axis of the handle is in-line with the central axis of the "coiled projection" that is shaft 104).

However, Mollenauer et al. do not disclose a sharpened tip including an exposed, tapered, and closed opening or an opening with at least a portion dimensioned to wedge and hold a suture, having a central portion with a tapered configuration, or comprising a tapered opening, where the sharpened tip includes at least one flat surface. Beyer et al. teach, at least in figures 2 and 3 and in col. 2, line 61 to col. 3, line 9; a device with a sharpened tip including an opening (7) that is exposed, tapered, and closed; or has at least a portion dimensioned to wedge and hold a suture, or is tapered from a distal closed edge to a proximal closed edge (at 20). The opening is positioned within a flat surface (14) of the sharpened tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the opening of the device of Mollenauer et al., so that it has the tapered configuration as taught by Beyer et al. Such an opening would enhance the trapping of a suture at a selected point, so that a user can manipulate the suture and sharpened tip with better control during suturing (i.e., the suture would less likely move inadvertently in an opening as taught by Beyer et al.). Moreover, modifying the sharp tip of the device, so that it has at least one flat surface would allow the device to have a small cross-sectional profile for penetration of tissue while carrying a suture through the penetration.

However, Mollenauer et al. in view of Beyer et al. do not disclose that the opening is continuously tapered as claimed. Zocher teaches, at least in figure 8 and in col. 3, lines 42-52, a needle with an eye that is continuously tapered ("substantially conical"), and like Beyer et al., the eye is offset from the longitudinal axis of the needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Zocher, to modify the eye of Mollenauer et al. in view of Beyer et al., so that is continuously tapered as claimed. Such an eye configuration would allow focused direction of a suture to the narrow portion of the eye, where improved support for the suture is provided during movement of the needle and suture.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. (5,562,685) in view of Orthwine (2,416,117), and further in view of Leighton (1,055,058). Mollenauer et al. disclose the invention substantially as claimed. Mollenauer et al. disclose, at least in figures 1 and 12 and in col. 9, line 37 to col. 10, line 5; a suturing device including a handle (102 or 12) extending along axial direction, an elongated shaft (104) with a distal end and extending along an axial direction, a sharpened tip (106 or 104) attached to (i.e., joined to) a distal end of the elongated shaft, where the sharpened tip (106) includes an exposed and closed opening (108) configured to trap a suture at a selected point. However, Mollenauer et al. do not disclose that the opening includes a tapered configuration with central axial region that is narrower than proximal and distal regions along a direction perpendicular to the axial direction to trap a suture at a selected point within the opening and to permit the suture

to pass lengthwise through the opening. Orthwine teaches in the figures and in col. 1, lines 12-29, a needle opening including a tapered configuration having central axial region ("restriction") that is narrower than proximal and distal regions (6, 7) along a direction perpendicular to the axial direction to trap a suture at a selected point within the opening and to permit the suture to pass lengthwise through the opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Orthwine, to modify the opening in the device of Mollenauer et al., so that the opening is configured as claimed. Such an opening would ease threading of the needle and allow a suture or thread to be retained by the needle.

However, Mollenauer et al. in view of Orthwine do not specifically disclose that the central axial region is open, although it does open upon passage of a suture through the region. Leighton teaches in figures 1-3 and lines 93-98; an opening in a needle that includes an open central region (5). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Leighton, to modify the central axial region of the opening in the needle of Mollenauer et al. in view of Orthwine. Such a modification would ease passage of the suture along the opening between the proximal and distal regions.

9. Claims 21-24, 27-29, 31, and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. in view of Beyer et al. and Zocher, and further in view of Yoon (5,437,680). Mollenauer et al. in view of Beyer et al. and Zocher disclose the invention substantially as claimed, where the device does not allow for independent positioning of the needle when the needle is attached to the shaft (i.e., the needle and

the shaft are joined to form a unitary structure). However, this combination does not disclose that the sharpened tip with an opening or the needle with a through opening is detachable from the distal end of the elongated shaft, where the elongated shaft is detachable from a handle. Yoon teaches, at least in figures 16 and 17 and in col. 9, line 65 to col. 10, line 7; a device with a handle (112) and an elongated shaft (104) including a detachable or separable needle (94) at the distal end of the shaft and holding a suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Yoon, to modify the device of Mollenauer et al. in view of Beyer et al. and Zocher, so that the sharpened tip with an opening or the needle with a through opening is detachable from the distal end of the elongated shaft. A needle with a suture detached from the elongated shaft would allow a surgeon to manipulate the needle itself for stitching of tissue without any physical interference from the elongated shaft. Also, the elongated shaft would be capable of receiving new or replacement needles. Additionally, it would be obvious to one having ordinary skill in the art at the time the invention was made, to include a handle that is detachable from the elongated shaft of Mollenauer et al. Such a configuration would allow disassembly of components of the device for cleaning, sterilization, and/or replacement of the components.

Response to Amendment

10. Applicant's arguments with respect to claims 1, 3, 4, 6, 7, 9, 12, 13, 16-18, 21-24, 27-29, 31, 55, and 57-60 have been considered but are not persuasive. That is, at least Mollenauer discloses a suturing device including, inter alia, a sharpened tip attached to a distal end of the shaft, and where the tip is immovable relative to the handle and the

shaft (i.e., the tip, handle, and shaft are joined to form a unitary structure). The term "attach" has been given its broadest reasonable interpretation, which is based on the dictionary or thesaurus of the ENCARTA World English Dictionary. The ENCARTA dictionary defines "attach" to include to "add something to something else: to append or fasten one thing to another; while the thesaurus states that "attach" is synonymous with "join" or "connect." In short, Mollenauer discloses a tip that is joined to or connected to a shaft.

With respect to arguments regarding the teachings of Mollenaer and Yoon: First of all, Mollenauer indeed discloses a device that does not allow for independent positioning of the needle when the needle is attached to the shaft. Also, the Examiner agrees with the Applicant in that Yoon's device allows for independent positioning of the needle relative to the shaft, i.e., the needle is detachable from the shaft. However, once the needle and the shaft of Yoon are connected, it can be said again, that the device does not allow for independent positioning of the needle when the needle is attached to the shaft. In this sense then, Yoon provides a teaching regarding a detachable needle that also does not allow independent positioning of the needle when attached to the shaft.

In any case, the claims are newly-rejected under 35 U.S.C. 112, since the specification does not support the limitations of the amended claims, and there is an apparent contradiction (i.e., a degree of indefiniteness) within the claims, where a tip or needle is said to be immovable or not positionable relative to shaft and also detachable from the shaft.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773